AUG 9 - 2005

SCHILLER
SWITZERLAND

K051368

BR-102 plus 510(k) Summary

Submitter Information

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Name of Device

Trade Name:	BR-102 plus
Common Name:	NIBP Holter System
Classification Name:	Non-Invasive Blood Pressure Measurement System, 21 CFR §870.1130 , DXN, Class II

Legally-marketed predicate devices

Accutracker DX, **K913844**, SunTech Medical Instruments Inc.

Oscar 2 Model 222, **K003004**, SunTech Medical Instruments Inc.

The BR-102 plus is substantially equivalent to the above mentioned devices.

Description

The BR-102 plus is a portable, compact, lightweight, microprocessor based ambulatory blood pressure monitor. Two versions are available:

- Using auscultatoric and oscillometric signals. During cuff delfation auscultatoric and oscillometric signals are analysed by the microprocessor to determine the blood pressure, where the oscillometric measurement is used as a backup.
- Purely oscillometric method to use the device without a microphone. The oscillometric signals are analysed by the microprocessor to determine the blood pressure.

The device is worn or carried by the patient. The cuff is borne on the upper arm. An electrical pump inside the device generates the pressure in the cuff. The BR-102 plus is powered from two AA size recharchable NiMH batteries. The BR-102 plus initialises blood pressure measurements depending on a predetermined shedule (normally predetermined by a physician), or on demand (by using the start key). Each reading is stored in memory, allowing the physician to download all the results obtained during the study period after the study has concluded, to be analysed by the PC software. The readings are displayed on the display for a short time.

The associated MT-300 PC software provides the setup of the system. A measurement shedule can be defined with the MT-300 program and up-loaded into the BR-102 plus. All the settings can also be made on the device. After the ambulatory blood pressure study has been completed (up to 48h) the stored readings in the BR-102 plus are downloaded to the PC using the MT-300 program. The MT-300 programm provides the data in tabular and graphic form, as well as a patient report and statistical values.

Intended Use

The BR-102 plus is a non-invasive ambulatory blood pressure monitor. It uses auscultatoric and oscillometric signals to measure the blood pressure of human beings, or uses purely the oscillometric signals. Systolic, diastolic, mean arterial pressure and the heart rate are measured. The BR-102 plus is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult or adolescent patient's blood pressure over an extended period of time (up to 48h). The BR-102 plus can be used for patients of both sexes and all races.

The BR-102 plus should not be used with neonates.

Performance Data

Non-clinical tests:

The BR-102 plus has passed the tests according to the following standards:

- ANSI/AAMI SP10
- EN 60601-1
- EN 60601-1-2
- EN 60601-2-30
- EN 1060-1
- EN 1060-3

Clinical tests:

To verify the overall system efficiency the measurments of BR-102 plus are compared with manual auscultatory measurements as discribed in the SP10. For the same reason the "International Test Protocol for validation of blood pressure measuring devices in adults" of the European Society of Hypertension has been carried out.

The BR-102 plus has satisfactory passed all tests.

Conclusion

The results of the above mentioned tests demonstrates that the BR-102 plus is equivalent in safety and efficiancy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

Schiller AG, Switzerland
c/o Mr. Markus Buetler
Quality Assutance and Regulatory Affairs
Altgassa 68
P.O Box
Ch-6341 Baar
Switzerland

Re: K051368
Trade/Device Name: NIBP Holter System
Regulation Number: 21 CFR 870.1130
Regulation Name: Non- Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: July 22, 2005
Received: July 29, 2005

Dear Mr. Buetler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K051368

Device Name: BR-102 plus

Indications For Use:

The BR-102 plus is a non-invasive ambulatory blood pressure monitor. It uses auscultatoric and oscillometric signals to measure the blood pressure of human beings, or uses purely the oscillometric signals. Systolic, diastolic, mean arterial pressure and the heart rate are measured. The BR-102 plus is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult or adolescent patient's blood pressure over an extended period of time (up to 48h). The BR-102 plus can be used for patients of both sexes and all races.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051368